REMARKS

The references do not establish a *prima facie* case of obviousness.

There are three basic criteria to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.[1] Where a *prima facie* case of obviousness is not supported by the facts, as is the case here, the applicant is under no obligation to submit evidence of nonobviousness.[2]

The References do not teach all the elements of the claimed invention

All claim limitations must be taught or suggested by the prior art to establish *prima facie* obviousness of a claimed invention[3]. The Office alleges that Yoon teaches a method for screening a sample for the presence of *K. brevis*, applying an amplification process to the sample in the presence of a primer specific to a target nucleotide sequence unique to *K. brevis.* In support, the Office points to Yoon, page 11726, column 1, lines 8-14, which states:

> These data provide strong support, therefore, for the monophyly of fucoxanthin-containing and haptophyte plastids. Our results, using an **expanded data set** of *rbc*L sequences, is consistent with previous reports. The two genera of fucoxanthin-containing dinoflagellates, *Karenia* and *Karlodinium,* are paraphyletic at the base of haptophyte clade, a result that is also found in the *psb*A tree. (emphasis added)

No reading of this passage can support the contention that Yoon teaches a method of detecting *K. brevis* using any method. The passage merely asserts that the two **genera** (*Karenia* contains both *K. brevis* and *K. mikimotoi*) form a group that contains its most recent common ancestor, but does not contain all the descendants of that ancestor. The Office has not provided any evidence as to how one could deduce a nucleotide sequence unique to *K. brevis* using this information.

The Office also points to Fig.1 (A & B) for support. Fig. 1 A and B show the phylogeny of red algal and red algal-derived plastids using combined *psa*A and *psb*A sequences. Claim 16

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[1] MPEP §2143
[2] MPEP §2412
[3] MPEP §2143.03, citing *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

has been amended to include the limitation that the target nucleotide sequence is on the *rbc*L gene; accordingly Fig. 1 A & B are not relevant to the claimed method. However, the LogDet method used to infer the phylogeny does not reveal the sequences used, regardless of the genes relied upon to infer the phylogeny.

The Yoon authors deposited, *inter alia*, *Karenia brevis* rbcL gene partial cds in the GenBank Database.[4] The deposit consists of a 907 base long sequence, less than two-thirds of *Karenia's* rbcL gene.[5] The statement that two genera are paraphyletic, *i.e.* composed of some but not all members descending from a common ancestor, has been interpreted as "identifying a unique gene sequence associated with the organism *K. brevis*." Yet Yoon discloses that the Form I rbcL gene is the primitive (not derived) condition in dinoflagellates, emphasizing its ubiquitous nature. There is also no teaching of what portion, if any, of the sequence deposited in the GenBank Database is unique to *K.* brevis, or of any method to determine same. Simply stated, the references do not teach or infer that a unique sequence exists.

The Office's position is best summarized where it states that Yoon used RT-PCR to amplify sequences specific to *some* species and was applied to cultures obtained from various collections of algae, which were initially collected in the field. The Office then concludes that "when combined with the known sequence of the *rbc*L gene (Gene Bank Accession No. AY119786), it is obvious the methods of Yoon can be used for detecting sequences of *K. brevis*." (Final Action, page 22). Gene Bank Accession No. AY119786 clearly states that the listing contains only partial cds; it is incumbent upon the Office to show that the claimed target sequence is identified in the reference. Moreover, the claimed invention is not for detecting **any** sequence of *K. brevis*, but detecting **unique** sequences of the *rbc*L gene of *K. brevis.* Gene Bank Accession No. AY119786 does not disclose which sequences of the *rbc*L of *K. brevis* is unique.

Conclusion

The Office has not established a *prima facie* case of obviousness. The cited references do not contain all the recited in the claims, as originally presented or as amended; the references do not establish a proper motivation for their combination; and the Examiner has not established a reasonable expectation of success for combing the references. As Yoon remains the primary reference for all rejections, no combination of the remaining references can serve to render the

[4] Accession No. AY119786

claimed invention obvious. Accordingly all independent claims are presumed to be valid[6] and all claims depending there from are nonobvious as a matter of law.[7]

If the Office is not fully persuaded as to the merits of Applicant's position, a telephone call to the undersigned at (813) 925-8505 is requested.

Very respectfully,

SMITH & HOPEN

By: _____

Dated: December 15, 2006

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CERTIFICATE OF ELECTRONIC TRANSMISSION

I HEREBY CERTIFY that this Amendment B with a RCE is being electronically transmitted through EFS-Web to the United States Patent and Trademark Office, Art Unit: 1637, Attn: David C. Thomas on December 15, 2006.

Dated: December 15, 2006

April Turley

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[5] Application, page 3, line 28.
[6] MPEP §2142
[7] MPEP §2143.03